



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Medicare & Medicaid Services**

#### **42 CFR Part 493**

**[CMS-3355-RCN]**

**RIN 0938-AT55**

### **Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance; Extension of Timeline for Publication of Final Rule**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS); Centers for Disease Control and Prevention (CDC), HHS.

**ACTION:** Extension of timeline for publication of final rule.

**SUMMARY:** The Social Security Act (the Act) specifies that a Medicare final rule must be published no later than 3 years after the publication date of the proposed rule or interim final rule, as applicable, except under exceptional circumstances. In accordance with the Act, this document announces an extension of the timeline for publication of the final rule and includes a brief explanation of the justification for the variation.

**DATES:** As of **[Insert date of display at the Office of the Federal Register]**, the timeline for publication of the final rule to finalize the provisions of the proposed rule published on February 4, 2019 (84 FR 1536), is extended until February 4, 2023.

**FOR FURTHER INFORMATION CONTACT:** Sarah Bennett, CMS, (410) 786-3531 or Nancy Anderson, CDC, (404) 498-2741.

**SUPPLEMENTARY INFORMATION:** In the February 4, 2019, **Federal Register** (84 FR 1536), we published a proposed rule entitled “Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance”, which would update proficiency testing (PT) regulations under the CLIA to

address current analytes (that is, substances or constituents for which the laboratory conducts testing) and newer technologies. This proposed rule would also make additional technical changes to PT referral regulations to more closely align with the CLIA statute.

Section 1871(a)(3)(B) of the Social Security Act (the Act) requires the Secretary to publish a Medicare final rule no later than 3 years after the publication date of the proposed rule or interim final rule, as applicable, except under exceptional circumstances. In such circumstances, the Secretary may vary the final rule publication timeline if the Secretary publishes a **Federal Register** notice of the different timeline, including a brief explanation of the justification for the variation, by no later than the previously established timeline. To meet the 3-year timeline, the final rule would have to be published by February 4, 2022. For the reasons discussed below, we are unable to publish the final rule by February 4, 2022. In accordance with section 1871(a)(3)(B) of the Act, this document announces an extension of the timeline for publication of the final rule by 1 year until February 4, 2023.

Since the COVID-19 public health emergency was effective January 27, 2020, we prioritized our efforts to issue appropriate regulatory flexibility provisions to increase access to reliable and accurate testing relevant to COVID-19, while minimizing unnecessary regulatory burdens. This redirection continues to require considerable focus and resources, especially to prioritize the publication of notices relevant to COVID-19 and to provide guidance to laboratories involved in COVID-19 testing. Therefore, we cannot meet the February 4, 2022 deadline. However, we intend to publish the final rule by February 4, 2023. Extension of the timeline to allow for issuing the final rule is critical as the release of the final rule is anticipated, and we expect stakeholders, including the laboratory community and others, will react positively to the changes to the CLIA regulations. The practice of laboratory medicine has changed significantly since the PT regulations were published in 1992. There are several clinically important analytes in common use today for which PT was not required in the 1992 rule. The laboratory community is aware of this and other gaps that will be addressed by this final rule. Stakeholders are actively

requesting updates to the PT analytes, acceptance limits, and microbiology model and have frequently inquired about the status of the final rule since 2019. For these reasons and based on comments we received in response to the proposed rule, it is important to extend the timeline to issue this final rule to revise and update the CLIA PT regulations.

---

**Karuna Seshasai,**

Executive Secretary to the Department,

Department of Health and Human Services.

[FR Doc. 2022-00932 Filed: 1/18/2022 8:45 am; Publication Date: 1/19/2022]